13/Appeal Brief(3)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Bet 10-16-98

In re application of	:	
MICHAEL ROREGER	:	
Serial No. 08/737,111	:	Group Art Unit 1615
Filed October 25, 1996	:	Examiner E. Webman
COLLAGEN PREPARATION FOR THE CONTROLLED RELEASE OF ACTIVE SUBSTANCES	:	

APPELLANT'S BRIEF

This Brief is filed pursuant to the Notice of Appeal filed August 10, 1998.

REAL PARTY IN INTEREST

The real party in interest is the Assignee of the inventor, LTS Lohmann Therapie-Systeme GmbH.

RELATED APPEALS AND INTERFERENCES

Appellant is not aware of any other Appeals or Interferences which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

STATUS OF CLAIMS

The claims on appeal are claims 16 to 30. Claims 1 to 15 have been cancelled.

The claims on appeal are presented as an appendix to this Brief.

STATUS OF AMENDMENTS

An AMENDMENT AFTER FINAL REJECTION was filed June 9, 1998. This amendment was entered by the Examiner upon the filing of the appeal. See the Advisory Action issued by the Examiner on June 24, 1998.

SUMMARY OF INVENTION

The present invention provides a collagen preparation for the controlled release of one or more active substances (claims 16 to 23), a process for the preparation of the collagen preparation (claims 24 to 27) and to methods for using the collagen preparation 28 to 30). The background of the present invention is described at pages 1 to 3 of the specification. With this background in mind, it was the object of the present invention to find a collagen preparation which is not only suitable for a certain active substance, a certain active substance combination, or a certain release profile

but also permits - for a great variety of uses - a wide-ranging, reliable control of the active substance release adapted to the respective problem. The solution was found in a collagen preparation for the controlled release of active substances which comprises mixtures of acid-insoluble collagen having different molecular weight distributions. See page 3 of the specification, the last ten lines.

The claims on appeal adequately define the invention and any position to the contrary was withdrawn by the Examiner in the Advisory Action issued June 24, 1998.

ISSUES

The sole issue on appeal is whether the claimed subject matter may properly be considered to be obvious to one of ordinary skill in the art within the meaning of 35 U.S.C. 103 from the teachings of Luck et al., U.S. Patent No. 4,619,913 in view of Wallace et al., U.S. Patent No. 4,789,663.

GROUPING OF CLAIMS

The claims on appeal stand or fall together.

APPELLANT'S ARGUMENT

The claims on appeal are rejected by the Examiner as lacking patentability under the provisions of 35 U.S.C. 103(a) over Luck et al. in view of Wallace et al..

It is the position of Appellant that the Examiner's rejection is unsound and may not properly be sustained for the reasons set forth herein.

The Luck et al. patent discloses that abnormal solid cellular growth, particularly tumors or adjacent tissue that may contain tumor cells, are treated by injecting into the abnormal growth area or tissue suspected of containing tumor cells, a sufficient amount of a cytotoxic drug dispersed in a stable, flowable, proteinaceous matrix. The proteinaceous material which can be employed is generally described in Luck et al. at column 3, lines 19 to 27. The disclosure of Luck et al., however, contains no information whatsoever directing one skilled in the art toward the employment of mixtures of acid-insoluble collagens or collagen fractions that have different molecular weight distributions.

In accordance with the present invention, for the controlled release of an active substance to or via the skin by means of collagen preparations, a special mixture of acid-insoluble collagens or collagen fractions is used which have different molecular

weight distribution and which are obtained in particular by alkaline decomposition. Such mixture of fractions from acid-insoluble collagen of different molecular weight distribution better takes into account the different requirements of different active substances, active substance combinations, and release characteristics than has previously been the case. Appellant respectfully submits that there is no suggestion whatsoever for this concept in the teachings of the Luck et al. patent.

Appellant respectfully submits also that the same argument applies to Wallace et al. and that the teachings of Wallace et al. certainly do not make up for the deficiencies of the teachings of the Luck et al. patent.

Wallace et al. teaches a method of repairing bone defects by the use of suspensions containing purified atelopeptide, reconstituted, fibrillar skin collagen or bone collagen powder or mixtures thereof. The preparation of collagen of Wallace et al. is a composition derived from either or both of two sources, bone and skin. The bone derived collagen is prepared from demineralized bone (DMB), and consists essentially of Type I collagen having the telopeptides effectively removed. It is obtained by treating DMB with a non-collagenase protease, such as trypsin, which both destroys factors mediating inductive repair and removes the telopeptides. The skin derived collagen is chiefly Type I collagen which includes a small amount of Type III and is typically obtained from calf skin. Here also, however, the teachings of the Wallace

et al. patent do not provide any suggestion of the concept of the present invention in which a special mixture of acid-insoluble collagens or collagen fractions is used which have different molecular weight distributions which are obtained, in particular, by alkaline decomposition.

Nowhere in the Luck et al. or Wallace et. documents can it be deduced that mixtures of acid-insoluble collagens of different molecular weight distribution are particularly useful material, for whatever purpose.

Thus, Appellant respectfully submits that the teachings of the Luck et al. and Wallace et al. patents in combination cannot properly be said to be suggestive of the subject matter of the present invention. Thus, the Examiner's rejection is unsound and should not be affirmed by the Honorable Board.

Respectfully submitted,

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APPENDIX

16. A collagen preparation for the controlled release of active substance which comprises at least one active substance and a mixture of acid-insoluble collagen-fractions each fraction having a different mean molecular weight and said fractions being obtained by alkaline decomposition.

17. A collagen preparation according to claim 16, wherein the collagen preparation comprises a plurality of active substances.

18. A collagen preparation according to claim 16, comprising an adjuvant selected from the group consisting of viscosity regulators, binders, humectants, softening agents, penetration enhancers, preservatives, disinfectants, pH-regulators, antioxidants, active substance stabilizers, oils, fats, waxes, emulsion stabilizers, odorous substances, dyes, inert fillers and mixtures thereof.

19. A collagen preparation according to claim 16, wherein the insoluble collagen is telopeptide-free, native, uncross-linked Type-1-collagen.

20. A collagen preparation according to claim 19, wherein the insoluble collagen is a product obtained from calfskin by alkaline decomposition.

21. A collagen preparation according to claim 16, in the form of powders, dusts, microparticles, fibers, flakes, foams, sponges, needles, rods, tablets, gels, creams, single-layer films, or laminates.

22. A collagen preparation according to claim 21, which comprises a combination of different forms of the collagen in order to obtain a desired kinetics of active substance release.

23. A collagen preparation according to claim 16, which is bioadhesive.

24. A process for the preparation of a collagen preparation according to claim 16, which comprises combining at least one active substance with a mixture of acid-insoluble collagen-fractions and subjecting such combination to spray drying, freeze-drying, coating or casting with subsequent drying, phase separation and coacervation processes, compression, or filling into containers.

25. A process according to claim 24, wherein the active substance release is controlled by the mixing ratio of acid-insoluble collagens having different mean molecular weights.

26. A process according to claim 24, wherein the active substance release is controlled by dissolution or swelling and subsequent erosion of the collagen preparation.

27. A process according to claim 24, wherein the active substance release is controlled by the biodegradation of the collagen preparation.

28. A method for the treatment of a wound which comprises applying to the wound a collagen preparation as defined in claim 16.

29. A method for the use of a collagen preparation as defined in claim 16, which comprises applying said collagen preparation to intact skin.

30. A method for the use of a collagen preparation as defined in claim 16, which comprises implanting or injecting said collagen preparation into a living organism.--

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PATENT OFFICE FEE TRANSMITTAL FORM

Honorable Commissioner of Patents and Trademarks,
Washington, D.C.

COPY, FINANCE DIV., USPTO
CHARGE DEFICIENCIES
TO DEPOSIT ACCT. # 23-0975

Sir:

Attached hereto is a check in the amount of $310.00 to cover Patent Office fees relating to filing the following attached papers:

Appeal Brief. . . . . $ 310.00

A duplicate copy of this paper is being submitted for use in the Accounting Division, Office of Finance.

The Commissioner is authorized to charge any deficiency or to credit any overpayment associated with this communication to Deposit Account No. 23-0975, with the EXCEPTION of deficiencies in fees for multiple dependent claims in new applications.

Respectfully submitted,

THE COMMISSIONER IS AUTHORIZED TO CHARGE ANY DEFICIENCY IN THE FEE FOR THIS PAPER TO DEPOSIT ACCOUNT NO. 23-0975.

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